IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Gao et al.	GROUP ART UNIT:	1615
SERIAL NO.:	09/451,641	CONFIRMATION NO.:	9327
EXAMINER:	Tran	ATTORNEY DOCKET NO.:	3169/1/US (PC010664)
FILED:	November 30, 1999		
TITLE:	CELECOXIB COMPOSITIONS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 21, 2006

RESPONSE TO OFFICE ACTION

Sir:

In response to the Office action of September 22, 2006, please consider the following remarks. A Request for Continued Examination is also submitted herewith.

Claims 1-10, 12-50, 72-75, 84, and 86-90 are currently pending. Claims 1, 2, 4-10, 12-50, 72-75, 84, and 86-90 stand rejected under 35 U.S.C. §103(a) as unpatentable over Karim et al., AAPS Annual Meeting Contributed Papers Abstracts, 1997 ("AAPS") in view of Black, EP 0 863 134 ("Black") or Plachetka, U.S. 6,586,458 ("Plachetka") or Block et al., U.S. 6,440,967 ("Block"), and under §103(a) as unpatentable over AAPS in view of Black and Zhang et al., U.S. 5,543,099 ("Zhang"). Claim 3 stands objected to as being dependent upon a rejected base claim.

Reconsideration is respectfully requested of the rejection of claims 1, 2, 4-10, 12-50, 72-75, 84, and 86-90 under §103(a) as unpatentable over AAPS in view of Black or Plachetka or Block and of the rejection of claims 1, 2, 4-10, 12-50, 72-75, 84, and 86-90 under §103(a) as unpatentable over AAPS in view of Black and Zhang.

Claim 1 is directed to a pharmaceutical composition. Claim 1 requires, *inter alia*, particulate celecoxib having a distribution of celecoxib particle sizes such that D_{90} of the particles is less than 200 μm. None of the cited references teach this particle size distribution.

The Office states, on page 3 of the May 17, 2005 Office action and on page 2 of the January 13, 2006 Office action, that "AAPS teaches a celecoxib (COX-2 inhibitor) formulation that exhibits a c_{max} values of 1527 and 1077 ng/mL, and a T_{max} of 1.9 hours." This is not correct. Applicants again respectfully point out that the c_{max} value of 1077 ng/mL refers to ***unchanged*** celecoxib, while the c_{max} value of 1527 ng/mL refers to total [^{14}C] – that is, it is ***not limited to unchanged celecoxib***.

A *prima facie* showing of obviousness requires, *inter alia*, that the cited references describe or suggest every limitation of the claimed invention. See MPEP 2143. Applicants respectfully assert that the Office has not made a *prima facie* showing that claim 1 is obvious in view of the AAPS reference and Black. The Office has not because it cannot.

A reference "may qualify as a prior art reference under §103, but **only for what is disclosed in it**." Reading & Bates v. Baker Energy Resources, 748 F.2d 645, 652 (Fed. Cir. 1984) (emphasis added). In Reading & Bates, a promotional brochure admitted to be prior art advertised a process set forth in a patent, but did not enable one to practice the invention of the patent. "The mere fact that the ... brochure, a one-page promotional brochure, boasts the ability and results of the process of the ... patent is insufficient, as a matter of law, to constitute an enabling disclosure of the process of the ... patent." Id. For similar reasons, Applicants assert that if the AAPS reference is prior art against the claims of the subject application, **it qualifies as prior art only for what is disclosed in it**. The AAPS reference merely discloses that 300 mg of celecoxib were administered "as a capsule" and the pharmacokinetic parameters c_{max}, T_{max}, $t_{1/2}$ and $AUC_{(0-48)}$ observed upon such administration. The reference is silent as to the nature of the celecoxib, including whether it is in particulate form and if so, what the particle size distribution is. Indeed, as the Office noted, "AAPS does not expressly teach the particle size distribution... ." Furthermore, the AAPS reference is silent regarding the nature of the capsule; whether the celecoxib was formulated in any way; what excipients, if any, were present in the capsule. Indeed, it is not clear from the AAPS reference whether the celecoxib was in solid particles, in suspension, or in solution.

Applicants respectfully submit that the combination of what is disclosed in the AAPS reference and Black or Plachetka or Block do not recite every element of claim 1. Zhang does not cure this deficiency, as Zhang also does not describe celecoxib particles having the required particle size distribution. Thus, Applicants respectfully submit that the Office has not shown that claim 1 is *prima facie* obvious in view of these references.

The Office asserts that "the burden is shifted to applicant to show that the formulation of AAPS does not have the claimed particle size distribution, as well as the detrimental effect and/or unexpected results over the particle size distribution, because AAPS teaches the oral formulation of celecoxib having the claimed c_{max} and T_{max} values." Applicants respectfully submit that because the Office has not shown that claims 1, 2, 4-10, 12-50, 72-75, 84, and 86-90 are *prima facie* obvious, shifting the burden to Applicants is improper. See MPEP 2142. Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 4-10, 12-50, 72-75, 84, and 86-90 be withdrawn.

Applicants respectfully acknowledge the Office's comments regarding claim 3. However, in light of the comments above, Applicants respectfully assert that claim 1 is not obvious, and is patentable, and therefore respectfully request that the objection to claim 3 be withdrawn.

Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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